K080717

SECTION 3

Summary of Safety and Effectiveness

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MAR 27 2008

Sponsor: EMcision Ltd.

Contact Person: Nagy Habib, MD
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Du Cane Road
London, W12 0HS
United Kingdom

Summary Prepared: January 25, 2008

Trade Name: Habib Hexablate 10

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification: Class II per 21 CFR 878.4400

Product Code: GEI

Previously cleared device: EMcision Habib Hexablate (K071103)

Intended Use:

The Habib Hexablate 10 is intended to be used to assist in coagulation of tissue during intraoperative surgical procedures.

Description:

The Habib Hexablate 10 is a bipolar radiofrequency (RF) device that consists of a handle and an array of seven parallel electrodes which extend out from the handle. The electrode configuration consists of six electrodes in a ring and one electrode in the center of the ring. The Habib Hexablate 10 has an attached cable which connects the device to an RF Generator. The electrodes are inserted into tissue and the tissue is coagulated using RF power. The Habib Hexablate 10 is designed for use in surgery and is a single use device.

Technological Differences:

The Habib Hexablate 10 has the same basic technological characteristics as the Habib Hexablate. Both devices use bipolar RF energy through a number of electrodes to create a volume of coagulated tissue. The primary difference is in the size of the coagulation zone created

by each device. The Habib Hexablate 10 also uses aspiration through the center electrode to remove fluids and gases from the center of the coagulation zone. The only difference between the previously cleared device and the new modified device is that the previously cleared device has a diameter of 20mm and the Hexablate 10 device has a diameter of 10mm.

Performance Data:

Performance testing was done to ensure that the Habib Hexablate 10 functions as intended and meets design specifications. Sufficient data was obtained to show that the Hexablate 10 meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Emcision, Ltd.
% Underwriters Laboratories, Inc.
Mr. Morten S. Christensen
455 East Trimble Road
San Jose, California 95131

MAR 2 7 2008

Re: K080717
Trade/Device Name: Habib Hexablate 10
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 27, 2008
Received: March 13, 2008

Dear Ms. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2
Indications for Use Statement

Indications For Use Statement

510(K) Number (if known) K080717

Device Name Habib Hexablate 10

The Habib Hexablate 10 is intended to be used to assist in coagulation of tissue during intraoperative surgical procedures.

Prescription Use ✓ OR Over the Counter Use _____
(per 21 CFR 801.109)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080717